REMARKS/ARGUMENTS

Claims 1-4 and 7-23 were pending at the time of the mailing of the outstanding Office Action. Claims 1-3, 8, 10, 11 and 16-23 are withdrawn from consideration. By this amendment, no claims have been added or cancelled. Claims 9 and 14 have been amended.

In the Office Action of 4 September 2008, claims 4, 7, 9, and 12-15 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 21-24 of co-pending US App. No. 10/706,717, as being unpatentable over claims 1-3, 5, 7-9 and 16-19 of co-pending US App. No. 10/596,797, as being unpatentable over claims 1-9 and 11 of co-pending US App. No. 10/908,729, as being unpatentable over claims 1-4 of co-pending US App. No. 11/221,322, and as being unpatentable over claims 1-4 of co-pending US App. No. 11/221,344. Claims 4, 7, 9, and 15 stand rejected under 35 U.S.C. § 102(b) as being anticipated by US Pat. No. 3,687,135 to Stroganov et al. (hereinafter "Stroganov"). Under 35 U.S.C. § 103(a), claims 12-14 were rejected as obvious over Stroganov.

Claim 14 stands rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner's position is that the term "about" preceding the weight percentage of each element does not appear in the specification and therefore claim 14 includes subject matter not described in the specification. While the Applicants maintain that additional portions of the specification such as paragraph 49 contain language which would indicate the approximate nature of the quantities of the alloy components, in the interest of economy in prosecution of the application, claim 14 has been amended to obviate this rejection.

The Applicants file herewith terminal disclaimers with regard to U.S. App. No. 10/706,717, U.S. App. No. 10/596,797, U.S. App. No. 10/908,729, U.S. App. No. 11/221,322, and U.S. App. No. 11/221,344. In light of these terminal disclaimers, withdrawal of the provisional rejections of claims 4, 7, 9, and 12-15 on the ground of nonstatutory obviousness-type double patenting is requested.

In maintaining the rejection under 35 U.S.C. § 102(b), the Examiner again states, "The limitations in the claim of 'inhibiting the proliferation of smooth human muscle cells wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel' are not given patentable weight, since the composition of Stroganov et al. has pharmaceutical use in bone surgery, and thus would be capable of the intended use of the claimed invention." The Examiner additionally states that the previously forwarded arguments regarding adaptation for implantation in a vascular vessel, inhibition of smooth muscle proliferation and intravascular liberation is unpersuasive. The Examiner alleges that these limitations are drawn to an intended use and do not impart any structural limitations on the composition. The Examiner also indicates that "adapted for" clauses are an example of language that suggest or makes optional, but does not require, a step or structure. The Examiner cites MPEP 2106 II in support of this contention. However, the cited section of the MPEP only indicates that such language "may raise a question of the limiting effect of the language in a claim." "Wherein" and "whereby" clauses are also included in this categorization. Clearly, the MPEP does not indicate that such clauses are always non-limiting. Indeed, such clauses are routinely used to expressly limit claims. Therefore, it is improper to consider the "adapted for" clauses to be *de facto* non-limiting.

Contrary to the Examiner's assertion, the phrase "adapted to be implanted in a vascular vessel" does provide a structural limitation, such as use as a stent for example, as discussed throughout the specification and as illustrated in Figs. 1-3. A bone screw as disclosed by Stroganov would clearly not be adapted for implantation in a blood vessel. The phrase "wherein the formulation is adapted for intravascular liberation after implantation in a vascular vessel" also provides a limitation on the structure in that the formulation must degrade within the vessel. Contrary to the assertion made in the final Office Action, this limitation also provides a structural limitation. As described in paragraph 0021, such behavior is caused by an at least substantially biodegradable carrier being present. While the Examiner maintained in the Advisory Action that this aspect does not distinguish over Stroganov, the fact that Stroganov's composition is biodegradable does not demonstrate that it would be capable of performing the same intended use as recited in the claims – adaptation for intravascular liberation. Therefore, these elements of claim 4 clearly provide structural limitations to the formulation and therefore should be given patentable weight.

As stated previously, Stroganov does not teach or suggest such elements. Stroganov instead provides a formulation that is intended and adapted for use in bone surgery, not for placement in vascular vessels. Stroganov does not provide any teaching or suggestion that an alloy of this composition is suitable for implantation in a vascular vessel under any conditions, or that it may be adapted for intravascular liberation as recited in claim 4. Because Stroganov does not teach or suggest such elements, claim 4 patentably distinguishes over Stroganov.

Similarly, the assertion in the Final Office Action that claim 15 does not impart a structural limitation is also incorrect. Claim 15 depends from claim 4. While claim 4 calls for the presence of one or more of yttrium (Y), neodymium (Nd) or zirconium (Zr), claim 15 additionally recites that the structure delivers yttrium to smooth muscle cells at specific levels. This is also a structural limitation, in that it not only specifically calls for the presence of yttrium, but it also calls for adaptation for delivery at specified levels. As discussed above, the presence of a biodegradable carrier provides delivery through biodegradation at a predetermined rate. As also discussed previously, Stroganov only discloses the use of their composition for joining bone fragments and to stimulate bone growth. Stroganov does not teach or suggest the delivery of yttrium to smooth muscle cells, and therefore, Stroganov also does not teach or suggest the delivery of the specified amounts of yttrium to smooth muscle cells as recited in claim 15.

Claim 9 has also been amended to specify that yttrium (Y) is present in an amount between 3.7 and 5.5 weight percent of the formulation. As noted in the final Office Action, Stroganov provides an example of a magnesium alloy containing 1.6 weight percent Y. This is well below the range now recited in claim 9.

Therefore, claims 4, 7, 9, and 15 patentably distinguish over US Pat. No. 3,687,135 to Stroganov et al. Withdrawal of the rejection of these claims under 35 U.S.C. § 102(b) is respectfully requested.

Claims 12-14 stand rejected under 35 U.S.C. §103(a) as being obvious over Stroganov. It is alleged in the final Office Action that a person of ordinary skill in the art would have found it

obvious to arrive at the present formulations as recited in claims 12-14 based on Stroganov's disclosure of the use of a composition containing rare earth metals in the range of 0.4%-4.0% by weight. The Applicants reiterate that the teachings of Stroganov have not been properly considered as a whole and therefore the desirability of its modification has been found with the aid of hindsight provided by the claimed invention.

As stated previously, Stroganov does not provide that the composition in question inhibits the proliferation of human smooth muscle cells. To the contrary, Stroganov is silent regarding the effect of such a composition on smooth muscle cells and actually indicates that the composition *stimulates* the proliferation of tissue, specifically bone tissue (Stroganov, column 2, lines 10-12). Stimulation of tissue growth in a vascular vessel would be undesirable, as likely triggering restenosis (see paragraph 0005 of specification). Therefore, Stroganov teaches away from use of the recited compositions adapted as a vascular vessel implant by providing a composition that stimulates cell growth instead of inhibiting it. A person having ordinary skill in the art would not have had a reasonable expectation of success in using Stroganov's composition in the present invention.

In apparent response to the argument above, the Examiner stated in the Advisory Action, "the teaching in Stroganov of stimulating bone growth does not exclude its compositions from being used for the inhibition of proliferation of smooth muscle cells." However, this places a burden on the Applicants which the Examiner must properly bear regarding the establishment or non-establishment of obviousness of the claims. The Applicants are not required to rebut a case of obviousness over Stroganov unless and until the Examiner establishes a *prima facie* case that one of ordinary skill in the art would have found the claims obvious at the time of the invention. The Applicants maintain that the Examiner has not established such a *prima facie* case. The Examiner has not established any suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the teachings of Stroganov to arrive at the present invention. That is, there is no suggestion or motivation for one of skill in the art to modify a bone growth-*stimulating* composition and to adapt it for use in blood vessels to *inhibit* smooth muscle proliferation. First, as mentioned above, one of ordinary skill in the art would understand that the general suitability of a composition with regard to

treatment of bone would not be predictive of suitability of that same composition with regard to blood vessels. There must also be a reasonable expectation of success and the prior art reference or references must teach or suggest all of the claim limitations. (MPEP § 2143.)

As discussed above regarding claim 4, from which claims 12-14 depend, Stroganov does not provide any teaching or suggestion of the implantation of the composition in a vascular vessel or adaptation for intravascular liberation of the composition after implantation in a vascular vessel as claimed. As also stated previously, Stroganov clearly provides an upper limit of total rare earth metals of 4.0 % by weight (column 2, line 21) while the claimed invention provides a total rare earth weight percentage (yttrium plus non-yttrium rare earths such as neodymium) of 5.2 % (claim 12), 5.5 % (claim 13), or 6.3% (claim 14). It should also be noted that claim 14 has been amended to remove "about" from this claim to provide "Yttrium in an amount of 4.1 % by weight." Therefore, the amount of yttrium recited in claim 14 can not be said to overlap the range of rare earth metals (which includes ytrrium) of Stroganov .

Finally, as also stated previously, the lapse of 30 years between the issue date of Stroganov (29 August 1972) and the priority date of the present invention (13 November 2002), additionally demonstrates that the modification of Stroganov as suggested by the Examiner was not obvious to one of ordinary skill in the art at the time of the invention, despite well-publicized efforts to improve therapy for heart disease during this time period. For these reasons, claims 12-14 patentably distinguish over Stroganov. Withdrawal of the rejections under 35 U.S.C. § 103(a) is respectfully requested.

The final Office Action was electronically transmitted on 4 September 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. 4 January 2009 fell on a Sunday. Therefore, the Applicants hereby petition for a one month extension of time in making this response, as 5 January 2009 is the next business day following a deadline date that falls on a Saturday, Sunday or federal holiday. The Applicants also hereby make a conditional petition for any additional extension of time for response in the event that such a petition is required. The Commissioner is authorized to charge any fee required with this paper or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

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